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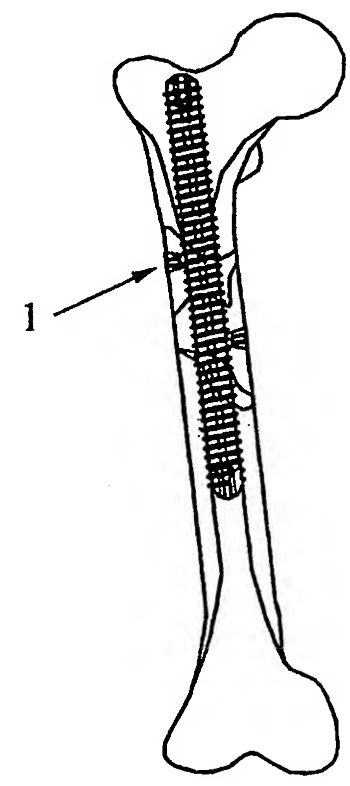
(54) Title: AXIAL INTRAMEDULLARY SCREW FOR THE OSTEOSYNTHESIS OF LONG BONES

(57) Abstract

Axial intramedullary screw (AIMS) for the operative treatment of fractures of long bones in human bone surgery (orthopaedic and traumatology) and veterinary surgery (for large and small animals), characterised by the feature that the osteosynthetic effect of stabilisation is created by the thread of the AIMS cutting into the internal cortical tubular part of the diaphysis of long bones in their axial direction. Application is simplified because of the two – wayness – it possesses two self–tapping tips on both sides and two screwdriver connections on them (3). It may be applied in a single type or in an interlocking type of AIMS for complex multi fragmented fractures. Transverse screws may approach central AIMS with different angles, they may be one–sided, two–sided, with cylindrical conical or threaded for compressive connection or combined (12, 13). AIMS is produced of stainless steel, titanium or resorptive osteosynthetic materials.



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AXIAL INTRAMEDULLARY SCREW FOR THE OSTEOSYNTHESIS OF LONG BONES

This invention is related to the wide area (Int. Cl. A61B) of orthopaedic surgery and traumatology for the operative treatment of fractures of long bones in humans and animals. Many different implants are used internationally and in different parts of the world. Among them are different bone screws (cortical, cancellous, malleolar, DHS, DCS etc.), bone plates (straight, angular etc), different types of external fixators and different intramedullary implants (Kuntcher nail, Rush nail, Ender nail, Kirschner wires implanted intramedullary, "gama nail" and for the last fifteen years the interlocking nail). The axial intramedullary screw (AIMS) system described here includes most of the operative indications for all formerly mentioned bone implants (fasteners), and may be used instead of them.

Technical field

The purpose of this AIMS bone implant from the technical point of view is the same as for other osteosynthetic devices. It is to maintain relative stability between the fractured bone parts with the purpose of creating optimal conditions for bone healing. During the procedure of application of any osteosynthetic device some basic mechanical principles are used to promote optimal osteosynthesis :

1. *Interfragmentary compression* (statical and dynamic) by lag screw, plate, external fixator etc.
2. *Gliding* (by Kuntscher, Rush and Endernail).
3. *Combination of the last two principles* - for example compressional lag screw and neutralisation plates.
4. *Neutralisation, unloading* (neutral support without compression or distraction) - used in the application of interlocking nails in multi fragmented fractures.

The AIMS system may be applied by the use of all the aforementioned mechanical principles depending on the type of fracture or local biomechanical needs.

Background Art

It is logical to compare the axial intramedullary screw (AIMS) with other intramedullary implants (Kuntscher nail, interlocking nail etc.) for the osteosynthesis of long bones (humerus, radius, ulna, femur, tibia, fibula, and also metacarpal and metatarsal bones and clavicle). I emphasize here the long bones because fastening two or more bone parts with a single small screw is in wide use. For instance the "Herbert screw" (USP 4,175,555) is applied to the small scaphoid bone of the hand, which is composed mainly of cancellous (spongy) bone with little diaphyseal part (without tubular cortical part). Therefore, it is the mechanical principle of osteosynthesis of AIMS which is different. The latter is two-sided, which is not the case with the Herbert screw. The same comment may be mentioned for the differences with Huebner screw (WO 94/16636) with variable pitch, applied also for small cancellous bones. The same

comment is also true for the compressional screw (WO 94/20040) which compresses the separated bone pieces (not long bone parts to one unit), and it is not applied intramedullary like the Kuntscher nail. In addition, they are all to small, with sizes like standardized (ISO) cortical or cancellous bone screws, for use in fixation of long bones. The current method of treatment of fractures of long bones by intramedullary fixation (Kuntscher nail, interlocking nail etc.) is based on two mechanical principles. AIMS is more compatible with use for these implants from the point of size, principles of implantation and operative indications. But there is also some differences in basic mechanical principles:

1. **Gliding** - fragments of the fractured bone are allowed to glide along the implant (Kuntscher nail, Ender and Rush nail) because the friction between the nail and bone is generally small. One form is described in patent application (HR P921004A A2). It is based on the combination of the classical interlocking intramedullary nail and flexible leading screw positioned in the central internal part of the nail. The thread of the central leading screw is smaller than the smaller diameter of the cortical bone and it is in contact with the intramedullary nail. So this flexible screw is not in contact with cortical bone (the main mechanical principle of AIMS) and it is not responsible for stability of bone fragments. Also the purpose of this device is distraction (elongation) of the femur and these characteristics are very different from AIMS.

2. **Locking** - with transverse screws in multi fragmented diaphyseal fractures. There are three functions for this:

   a/ Attainment of axial and rotator stability (interlocking Kuntscher nail, Verrigelungs Nagel)

   b/ Possible compression by transverse screw over central intramedullary nail. The best example is the "gama nail" described in different variations in many patent applications. For instance in EPO 0 441 577 A3 by the name "Intramedullary hip screw" and also in EPO 0 321 170 B1, where term "intramedullary screw" is related to transverse spongeosal screw through the femoral neck with the purpose of compression of the femoral head to a central femoral nail (short Kuntscher nail). These two characteristic are very different from the hereafter described variations of the interlocking AIMS.

   c/ Modular intramedullary nail (WO 96/02202) is composed 2 or 3 parts (nails) connected with conical connections, but it is different from the modular AIMS hereafter described because it is only a nail and not an intramedullary screw.

Disclosure of Invention

In distinction to all other intramedullary implants (Kuntscher and interlocking nail) - AIMS does not create axial and bending stability using the mechanical principles formerly described (gliding and locking). The

characteristic of the AIMS is that axial and bending stability is attained through neutralisation (unloading) by wide contact between threads of the AIMS cutting into the internal cortex of all fragments of the fractured bone. For the creation of rotatory stability it is possible also to apply one or more interlocking screws (Fig. 4 - Fig. 11). Therefore, it is possible to use AIMS for multi fragmented fractures and for the same indications as the Interlocking (Kuntscher) nail. As distinguished from other intramedullary implants AIMS is very rigid. The principles of the application of AIMS are very similar to other intramedullary implants, but it is also distinguished from them in some important features:

1. AIMS is connected ***by the thread to the internal cortical part of the long tubular bone***. This feature creates a very high degree of stability among the fractured parts of the bone, much higher than with other osteosynthesis devices and implants. AIMS transfers forces of load directly from proximal to distal bone fragments over a wide circumferential contact area. The same principle of load transmission over centrally positioned implants is also the case with the interlocking nail, but there is stress concentration in the area of the interlocking screws and the nail is more flexible and not as stiff as with the AIMS. As there are different intramedullary bone diameters, there are different diameters of AIMS (1 - 18 mm), different lengths, pitches of the thread, types of the thread (cortical, cancellous, metric, etc.). Despite this, in some cases there is a need for pre-reaming the medullary canal for adaptation before application of the correct AIMS - self-tapping or non-self-tapping (require a predrilled hole and cutting with a tap).

2. ***Two-wayness*** is the second distinguishing characteristic of AIMS. The screw may be hollow in the central part (Fig. 2 - 2) or not, with two - way self - tapping tips and thread cutters (Fig. 2 -3). On both sides there is also a screwdriver connection (sextant imbus, transverse or cruciate, Phillips, Torx etc.). Because of the two - wayness the operative procedure may begin retrogradely through the fracture gap from inside, and then, by the use of the hollow screwdriver over the guiding Kirschner wire, it will be returned from outside.

3. ***The central hollow*** of the AIMS may vary between 0.5 and 5 -10 mm according to its diameter. As well as the formerly mentioned guiding function, the Kirchner wire or wire cable may be used for axial static compression between two bone parts (proximal and distal). For this function there is a fastener composed of the compression spring with threaded hollow rod (inside the spring) connected to the back of the screwdriver with the Kirschner wire attachment (Fig. 3 - 5).

4. The connection of AIMS by the thread to the internal cortical part of the long tubular bone creates a very high degree of axial stability among the fractured parts. It is sufficient in some types of fractures.

5. However, it is possible to ***locking the AIMS by transversely applied screws*** in any directions by which additional rotatory stability is obtained (in intrarticular fractures or in those in metaphyseal areas).

6. In addition to an antirotational function of the transverse locking screws, it is possible also to produce compression by them between the lateral free bone fragments and centrally positioned AIMS (Fig. 11). The connection between the central AIMS and locking screw may be cylindrical (Fig. 6 - 11), conical (Fig. 8 -

12; Fig. 9, Fig 12 - 17) unloading (neutral) screw (Fig. 10) and compressive screw (Fig. 11). Each of these connections may approach the central AIMS perpendicularly or with some angle to it (Fig. 8 -13). Selection depends on the local biomechanical needs and this contributes to more operative possibilities for free bone fragment stabilisation.

Using the AO/ASIF classification of fractures as ABC types (Comprehensive Classification of Fractures of Long Bones, M.E.Mueller; M. Allgower, R. Schneider, H. Willenegger; Manual of Internal Fixation, Third Edition, Springer Verlag 1991) we can easy recognise a practical concordance with classification of AIMS. In practice we may use three types of AIMS:

Simple AIMS (Fig. 2, Fig. 3, Fig. 5). These are applicable for all fractures of type A (1,2 and 3) in the diaphyseal parts of long bones.

2. Interlocking AIMS

a) *One - sided* (Fig. 10, Fig. 11, Fig. 12). These are applicable for all fractures of type B (1,2 and 3) in the diaphyseal parts of long bones where is a need for additional fixation of a free bone fragment (Fig. 1 - 1) These are also applicable in some cases of intrarticular fractures of type B (1, 2 and 3).
b) *Two - sided* (Fig 4, Fig. 6, Fig. 7). These are applicable for all fractures of type A(1, 2 and 3) in distal parts of long bones and in intrarticular fractures type C(1, 2 and 3).
c) *Unipolar* (Fig. 6)
d) *Bipolar* (Fig. 7). These are applicable for all diaphyseal fractures of type C (1, 2 and 3) and in distal parts of long bones for intrarticular fractures of type C(1, 2 and 3).
e) *Combined - multiple and many - sided* (Fig. 8) are variable and composed of all formerly mentioned combinations. They are applicable mainly for complex fractures of type C. Transverse interlocking screws may approach the central AIMS by different angles.

3. Modular AIMS (twofold and threefold) is specially applicable for treatment of fractures on small metacarpal and metatarsal bones or in some cases of fractures in growing bones in children (for prevention of injury of the growth plate). With each part of this modular AIMS it is possible to screw in both directions. It is characterised by an axial conical connection between them (Fig. 12 - 14) and compression of the bone segments is induced over an axially-positioned additional transverse conical connection - interlocking screw (Fig. 12 - 15) through the hole of the axial conus (Fig. 12 - 16). The additional conical interlocking screw functions in derotation stability (Fig. 12 - 17).

Modes of AIMS application:

Two methods of operative procedure may be applied in the AIMS application:

1. *In a retrograde way* through the fracture gap from inside, and then by the use of a hollow screwdriver over the guiding Kirschner wire AIMS will be returned from outside bridging the fracture (Fig. 3).

2. *In an antigrade way* identical to the Kuntscher or Rush nail procedure of implantation through the great trochanter of the femur or major tubercule of the humerus. These AIMS may enter the bone from outside. They may possess a head or be without, they may be hollow or solid. They are very similar in form to standard (ISO) cortical or spongious screws although their size is much bigger. AIMS is applicable to human bone surgery and also in veterinary surgery for large animals (horses etc.) and small animals (dogs, cats, birds etc.). There are thus great variations in sizes and the diameter of AIMS may vary according to the internal diameter of the cortices of long bones (1 - 18 mm), and in length from 20 - 500 mm. The operative procedure begins through a standard approach to open reposition (Fig. 3 - 6). Then follows drilling a proximal hole through the great trochanter of the femur (or major tubercle of the humerus, or proximal tibia etc.) retrogradely from inside to outside. In the distal bone part a guiding and compressing Kirschner wire or wire cord is attached to a single cortical screw (Fig. 3 - 7). This is followed with retrograde application of AIMS to the proximal bone fragment over the attached wire (AIMS and screwdriver are hollow). After repositioning of the fractured parts, compression is made by the Kirschner wire with a compressive screw nut. Then follows screwing the AIMS over the fractured area to the distal fragment.

The materials in which AIMS may be produced are standard stainless steel for implants ISO 5832/6 5832/IV or 5832-8, or titanium for implants ISO 5832-3. A very important type of AIMS is produced from resorptive implant materials (polyglucoside, polylactide, PDS etc.). Such resorptive types are in the same form as the formerly described metallic AIMS, and they are very practical for young people and children in the treatment of fractures or corrective osteotomies for hip dysplasia or other deformities. The same applies to veterinary surgery.

CLAIMS

1. Axial intramedullary screws (AIMS) for the operative treatment of fractures of long bones in human bone surgery (orthopaedic and traumatology) and veterinary surgery (for large and small animals), characterised by the feature that the osteosynthetic effect of stabilisation is created over the thread of the AIMS cutting into the internal cortical tubular part of the diaphyses of long bones in their axial direction.
2. AIMS according to claim 1. characterised by two-wayness because it possesses on both sides a connector for a screwdriver (imbus - sextant, transverse or cruciate connection, Phillips or Torx).
3. AIMS according to claim 1. and 2. characterised by two-wayness because it possesses on both sides connections for selftapping - tips (cutter of the thread) or without it (non-self-tapping AIMS).
4. AIMS according to claim 1., 2. and 3. characterised by a central hollow through the entire length which may vary between 0.5 and 10 mm, for the purpose of guiding Kirschner wires or wire cord.
5. AIMS according to claim 1., 2. and 3. characterised by the fact that is whole, without a central hollow.
6. AIMS according to claim 1., 4. and 5. characterised by one - wayness (one direction - ess) because it possesses a head on one side.
7. AIMS according to claim 1., 2., 3., 4., 5. and 6. characterised by thread through its entire length.
8. AIMS according to claim 1., 2., 3., 4., 5. and 6. characterised by a thread on its sides (and not in the central part).
9. AIMS according to claim 1., 2., 3., 4., 5., 6., 7. and 8. characterised by transverse holes (interlocking AIMS), single or multiple with different angles to the axial axis of the AIMS.
10. Interlocking AIMS according to claim 9. characterised by transverse holes in cylindrical form.
11. Interlocking AIMS according to claim 9. characterised by transverse holes in conical form.
12. Interlocking AIMS according to claim 9. characterised by transverse holes in threaded cylindrical form.
13. Interlocking AIMS according to claim 9. characterised by transverse holes in threaded cylindrical form with conical widening in the beginning for the conical head of the transverse screw.
14. Transverse screw of the interlocking AIMS according to claim 9 characterised by application through central AIMS in cylindrical hole.
15. Transverse screw of the interlocking AIMS according to claim 9 and 11 characterised by conical tip and application through central AIMS in its conical hole.
16. Transverse screw of the interlocking AIMS according to claim 9 and 12 characterised by cylindrical tip and application through central AIMS in its cylindrical threaded hole.
17. Transversal screw of the interlocking AIMS according to claim 9 and 13 characterised by cylindrical threaded tip and conical widening of the head and application through central AIMS in its cylindrical threaded hole.

18. Modular (twofold or threefold) AIMS according to claim 9 characterised by axial conical connection between screw parts and identical transverse conical connection through it for derotation and compression.
19. AIMS according to claim 1 - 8 and 9 - 18 characterised by the material of which is made - stainless steel for bone implants ISO 5832/6or ISO 5832/IVor5832-8 or titanium ISO 5832-3.
20. AIMS according to claim 1 - 8 and 9 - 18 characterised by the material of which is made - resorptive material for bone implants (polyglucoside, polylactide, PDS etc.).
21. Screwdriver for application of AIMS according to claims 1 - 8 and 9 - 18 characterised by hollowness throughout its length.
22. Screwdriver for application of AIMS according to claims 1 - 8 and 9 - 18 and 21 characterised by compressing threaded rod, spring and attachment for Kirschner wire or wire cord.

FIG. 1

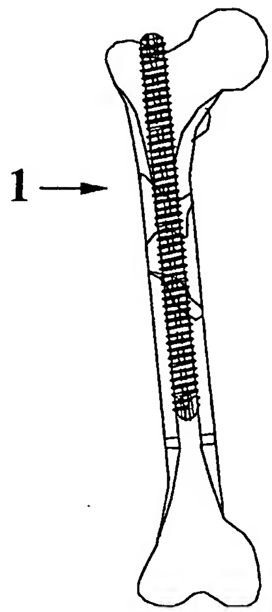


FIG. 2

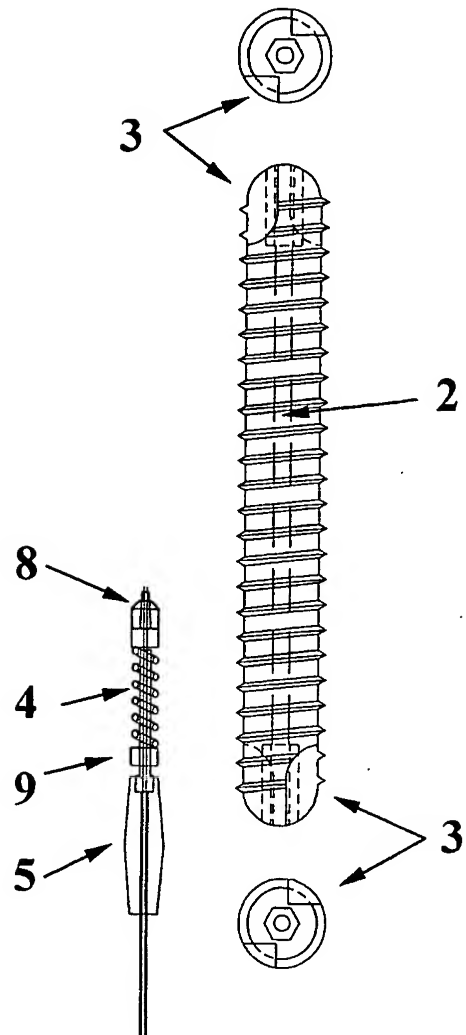
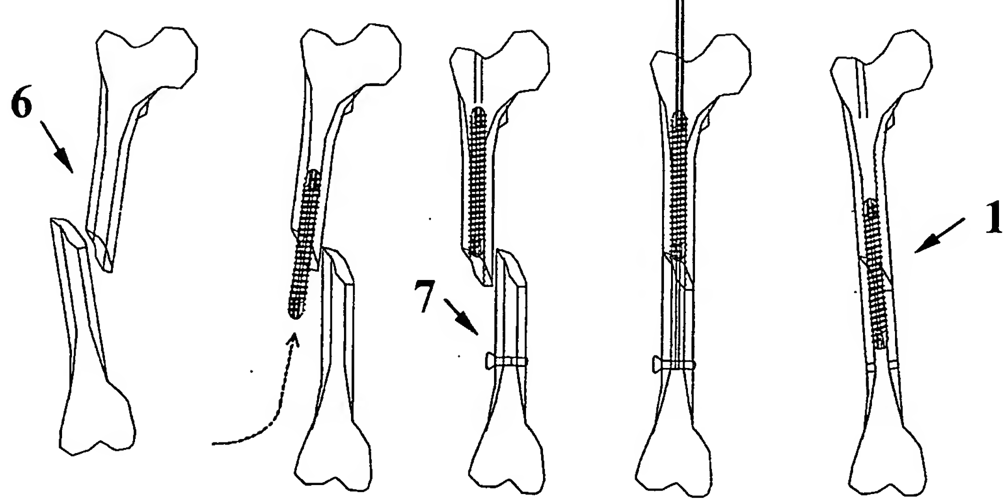


FIG. 3



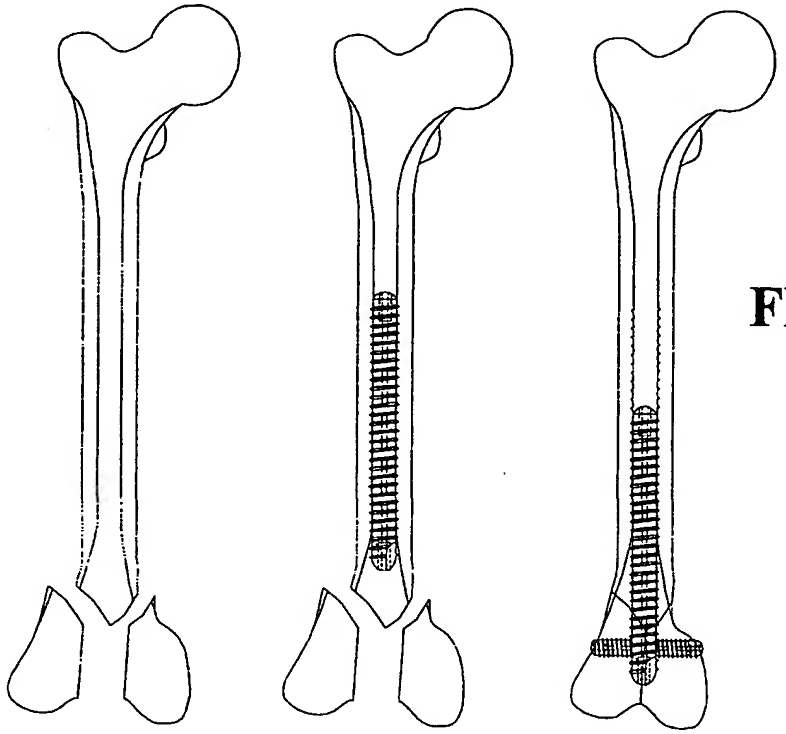


FIG. 4

FIG. 5

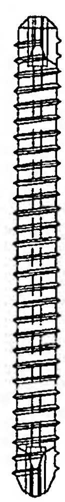


FIG. 6

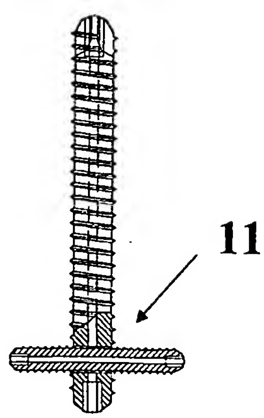


FIG. 7

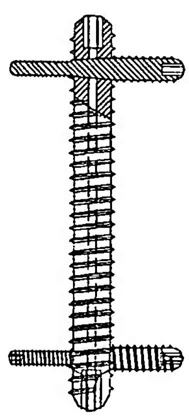


FIG. 8

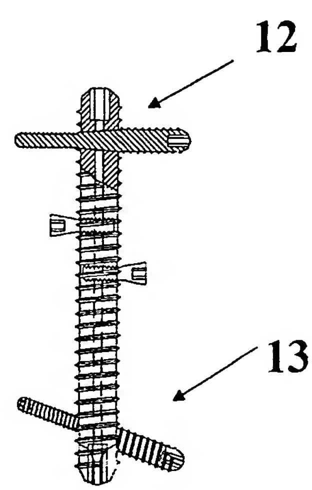


FIG. 9

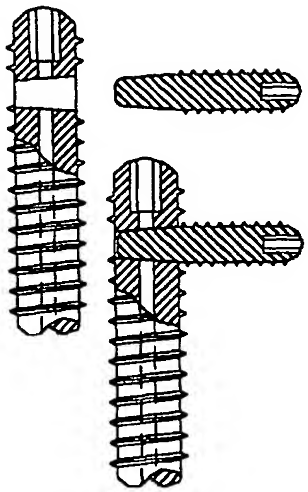


FIG. 10

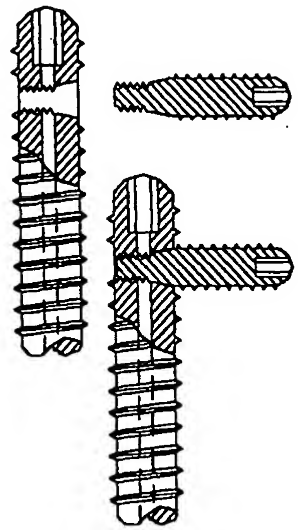
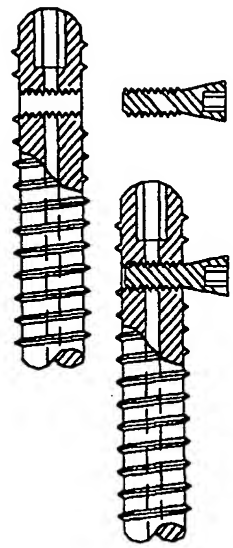
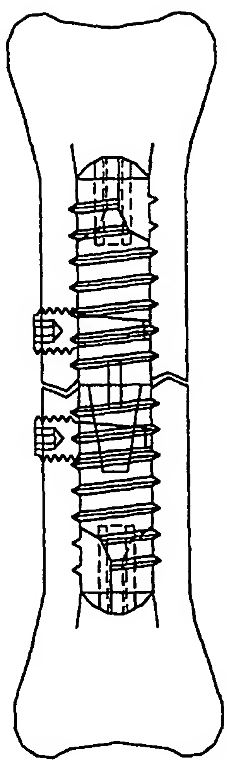


FIG. 11





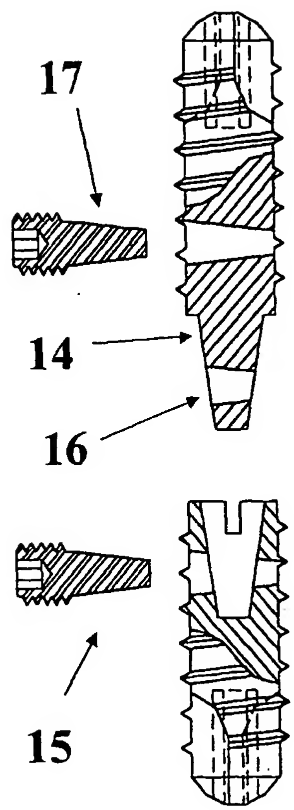
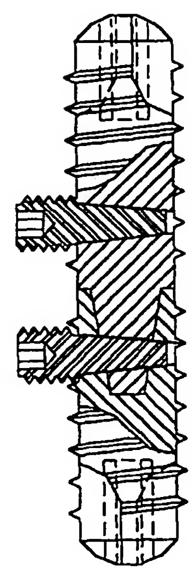


FIG. 12



INTERNATIONAL SEARCH REPORT

International Application No
PCT/HR 99/00033

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/72

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 4 016 874 A (E.J.MAFFEI AND D.W.PATCH) 12 April 1977 (1977-04-12) figures 1,2,5,11-13 column 3, line 9 - line 12 column 3, line 53 - line 56 column 1, line 57 - line 59	1-4,6,8,19,20 21
X	US 4 463 753 A (R.B.GUSTILO) 7 August 1984 (1984-08-07) column 5, line 29 - line 32; figures 1-2,5D-E	1,3,5
Y	EP 0 451 932 A (MECRON MEDIZINISCHE PRODUKTE) 16 October 1991 (1991-10-16) column 4, line 9 - line 26; figure 3	21

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[X] Further documents are listed in the continuation of box C.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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